UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

KM

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/240,675	02/02/99	BENOIT	P 017283/0123

HM22/0131

FOLEY AND LARDNER
3000 K STREET NW SUITE 500
P O BOX 25696
WASHINGTON DC 20007-8696

EXAMINER	
DEVI,S	
ART UNIT	**PAPER NUMBER**
1645	4

DATE MAILED: 01/31/01

Please find below and/or attached an Office communication concerning this application or pr ceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/240,675	Applicant(s) Benoit et al.
	Examiner S. Devi, Ph.D.	Group Art Unit 1645

☒ Responsive to communication(s) filed on *Jan 8, 2001* .

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *three* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *23-26* is/~~are~~ pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *23-26* is/~~are~~ rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☒ The specification is objected to by the Examiner.

☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☒ Interview Summary, PTO-413 (paper no. 13).

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Applicants' After-Final Amendment

1) Acknowledgment is made of Applicants' After-Final amendment filed 01/08/01 (paper no. 12) in response to the Final Office Action mailed 09/08/00 (paper no. 10), which has been entered.

Status of Claims

2) Claims 23-26 have been amended via the After-Final amendment filed 01/08/01.

Claims 23-26 are pending and under examination.

Withdrawal of Finality of the Office Action

3) The finality of the previous Office Action mailed 09/08/00 (paper no. 10) is hereby withdrawn for the reasons given below.

Instant claims are drawn to an isolated peptide or polypeptide of "SEQ ID NO: 1 or 2" or a portion thereof which specifically binds to the monoclonal antibody 64G12. Thus, as drafted currently, instant claims are directed to amino acid sequences or portions thereof. However, a review of the specification indicates that it lacks descriptive support for a peptide or polypeptide sequence of "SEQ ID NO: 1", because the sequence listing, Figure 2 and the description for Figure 2 on page 13 indicate that SEQ ID NO: 1 is a "nucleotide" sequence. It is further noted that paragraph 7 of the Tovey Declaration refers to peptides or polypeptides consisting of "the amino acid sequences ..... of SEQ ID NO: 1 ..... specifically bind to the monoclonal antibody, 64G12". However, this does not make sense in light of the description provided in the sequence listing, Figure 2 and the description for Figure 2 on page 13. The new rejections made below in this Office Action are necessitated by this defect. Other informalities in the instant specification are also pointed out, the correction of which would place the instant application in condition for allowance, pending obviation of rejections of record.

Telephonic Interview

4) Via a telephone conversation on 22 January 2001, Mr. Bernhard Saxe was requested to point to specific parts of the disclosure that provide descriptive support for the peptide of claim 24 (see paper no. 13). Applicants have not addressed the issue via telephone until the writing of this Office Action. Applicants are asked to note the new rejection made below with regard to this

issue.

Objection(s) Withdrawn

5) The objection to claims 23 and 25 made in paragraph 20 of the Office Action mailed 09/08/00 (paper no. 10) is withdrawn in light of Applicants' amendment to the claims.

Objection(s) Maintained

6) The objection to the drawings made in paragraph 7 of the Office Action mailed 09/03/99 (paper no. 7) is maintained for reasons set forth therein. Applicants state that they would respond to this objection upon allowance.

Rejection(s) Withdrawn

7) The rejection of claim 26 made in paragraph 14 of the Office Action mailed 09/03/99 (paper no. 7) and maintained paragraph 14 of the Office Action mailed 09/08/00 (paper no. 10) under 35 U.S.C § 112, first paragraph, as being non-enabled, is withdrawn in light of Applicants' amendment to the claim.

8) The rejection of claim 26 made in paragraph 15(b) of the Office Action mailed 09/03/99 (paper no. 7) and maintained paragraph 15 of the Office Action mailed 09/08/00 (paper no. 10) under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

9) The rejection of claim 24 made in paragraph 18 of the Office Action mailed 09/08/00 (paper no. 10) under 35 U.S.C § 102(b) as being anticipated by Orten *et al.* (*Biochemistry*, Eighth Edition, The C.V. Mosby Company, Saint Louis, pp. 57-90, 1970), is withdrawn in light of Applicants' amendment to the claim.

Rejection(s) Maintained

10) The rejection of claim 24 made in paragraph 19 of the Office Action mailed 09/08/00 (paper no. 10) under 35 U.S.C § 102(a) as being anticipated by Racaniello *et al.* (WO9203538), is maintained for reasons set forth therein and here below.

Applicants contend that the proposed amendment obviates the rejection. However, the Racaniello's "portion" of a polypeptide consisting of an amino acid sequence from position 27 to position 229 of the claimed SEQ ID NO. 2 meets the structural element of the instant claim as

amended and therefore, the new functional limitation introduced to the claim, i.e., the specific binding to the 64G12 antibody, is viewed as inherent to the "portion" of the polypeptide of the prior art. Although Racaniello *et al.* are silent about the binding of the prior art "portion" of the polypeptide to the specific monoclonal antibody, 64G12, recited in the instant claims, the prior art peptide or polypeptide is viewed as the same as the Applicants' peptide or polypeptide. Since the prior art peptide or polypeptide is structurally same as the one claimed in the instant claim, it is expected to bind to Applicants' specific monoclonal antibody, 64G12, which was inaccessible to Racaniello *et al.* at that time. The property of binding to the specific monoclonal antibody recited by the Applicants is inherent to the peptide or polypeptide of Racaniello *et al.*

Oath/Declaration

11) The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

Non-initialed and/or non-dated alterations have been made to the oath or declaration. See 37 CFR 1.52(c).

For example, see changes made the name of the inventor "Debborah MAGURE" and changes made to the citizenship of inventors Maguire, Meyer and Plavec.

Title

12) The title of the invention is not descriptive. The title is directed to the monoclonal antibodies to the interferon receptor whereas the claims are drawn to an isolated peptide or polypeptide of the extracellular portion of the human interferon receptor to which the monoclonal antibody deposited as ECACC 92022605 specifically binds. A new title reflective of the subject matter of the elected claims, --An isolated peptide or polypeptide of the extracellular portion of the human interferon receptor (IFN-R)--, is suggested.

Specification/Informalities

13) The disclosure is objected to because of the following informalities:

(a) There are discrepancies with regard to the SEQ ID numbers used for amino acid and nucleotide sequences used in the specification/sequence listing and in the instant claims. For

example, in the sequence listing, Figure 2 and the Figure 2 description, SEQ ID NO: 1 is characterized as a nucleic acid sequence. However, instant claims characterize SEQ ID NO: 1 as an amino acid sequence. Clarification/correction is needed so that a meaningful sequence search can be performed.

(b) In the drawings, Figures 2 and 3 are shown as containing two parts: Figure 2A and 2B and Figure 3A and 3B. However, the description on page 13 under the side heading "FIGURES", lacks references to the two panels of Figure 2 and 3, i.e., 2A and 2B as well as 3A and 3B [Emphasis in original]. Correction is requested.

(c) As per 37 C.F.R 1.74, it is suggested that Applicants replace the side heading "FIGURES" on page 13 with --Brief Description of the Drawing(s)-- [Emphasis in original].

(d) The use of the trademarks in the instant specification has been noted in this application. For example, see page 17: "Mono Q" and page 19, "Tween 20" (two occurrences). Although the use of trademarks is permissible in patent applications, the propriety nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

New Rejection(s)

Rejection(s) under 35 U.S.C. § 112, Second Paragraph

14) Claims 23-26 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

(a) Claims 23-25 are confusing, incorrect and indefinite in the recitation of a ".... peptide or polypeptide ..... of SEQ ID NO: 1". However, SEQ ID NO: 1 is characterized as a nucleic acid sequence in the sequence listing, Figure 2 and the Figure 2 description. It is unclear how the recited monoclonal antibody can react both with a fragment of an amino acid sequence and a nucleotide sequence. Clarification/correction is requested.

(b) Claims 26 which depends from claim 23 is also rejected under 35 U.S.C. §112, second paragraph, as being indefinite because of the indefiniteness identified above in the base claim.

Rejection(s) under 35 U.S.C. § 112, First Paragraph

15) Claim 24 is rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

The instant claims are directed to an isolated peptide or polypeptide consisting of an amino acid sequence from position 27 to position 229 of SEQ ID NO: 1 or 2, or a portion thereof having specific binding to the 64G12 monoclonal antibody. However, there appears to be no descriptive support in the instant specification as originally filed for such a peptide or polypeptide. Therefore, the claimed peptide or polypeptide is considered to be new matter. *In re Rasmussen*, 650 F2d 1212 (CCPA, 1981). New matter includes not only the addition of wholly unsupported subject matter but also, adding specific percentages or compounds after a broader original disclosure, or even omission of a step from a method. See M.P.E.P 608.04 to 608.04(c).

Applicants are respectfully requested to remove the new matter from the claim, or point to the specific parts of the disclosure as originally filed that provide descriptive support for the limitation.

16) Claims 23-26 are rejected under 35 U.S.C. §112, first paragraph, because the specification while being enabling for a peptide or polypeptide consisting of the recited fragments of "human" IFN-R of SEQ ID NO: 2 which specifically reacts with the monoclonal antibody identified under the accession no. ECACC 92022605, does not reasonably provide enablement for such a peptide or polypeptide of SEQ ID NO: 1. Evidence that instant claims fail to correspond in scope with that which Applicants regard as the invention can be found in the sequence listing, Figure 2 and the description for Figure 2 on page 13, wherein SEQ ID NO: 1 is identified as a nucleic acid or nucleotide sequence. This is inconsistent with the SEQ ID NO: 1 being recited or identified as a peptide or polypeptide sequence in the instant claims. This indicates that the invention disclosed in the disclosure is different from what is claimed in the instant claims. It is unlikely that the recited monoclonal antibody reacts specifically with an amino acid sequence (SEQ ID NO: 2) and also with the nucleotide sequence (SEQ ID NO: 1) that encodes SEQ ID NO: 2.

Furthermore, the scope of the peptide or polypeptide as claimed broadly encompasses a peptide or polypeptide fragment of the extracellular portion of any interferon receptor or a

portion thereof that binds specifically to the recited monoclonal antibody. However, the specification is enabled only for the claimed peptide or polypeptide or a portion thereof of a fragment of the extracellular portion of the "human" interferon receptor. See Figure descriptions, for example. That the scope of enablement for the claimed peptide or polypeptide fragment or a portion thereof is limited only to that originating from the human IFN-R is also evident from paragraph 4 of the Tovey Declaration. For example, the Tovey Declaration states that despite the fact that as much as 66% of the amino acids are conserved between bovine and human IFNAR1, the recited monoconal antibody "does not recognize bovine" IFN-R. Clearly, the full scope of the instant claims is viewed as non-enabled. One of ordinary skill in the art would not be able to make and use the claimed peptides or polypeptides or practice the full scope of the claims as claimed without undue experimentation.

Rejection(s) under 35 U.S.C § 102(a)

17) Claims 23 and 25 are also rejected under 35 U.S.C § 102(a) as being anticipated by Racaniello *et al.* (WO9203538) for the same reasons explained above in paragraph 10, because Racaniello's "portion" of a polypeptide consisting of an amino acid sequence from position 27 to 427 or position 1 to 229 of the claimed SEQ ID NO. 2 meets the structural element of the instant claims, as amended.

Objection(s)

18) Claims 23-25 are objected to for the following reasons:

(a) Claim 25 is objected to for capitalizing the recitation "OR" in line 4 of claim 25. Correction is requested.

(b) Claim 25 is objected to for not identifying the 64G12 monoclonal antibody by its depository accession number as in rest of the claims.

Remarks

19) Claims 23-26 stand rejected.

20) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center located in Crystal Mall 1 (CM1). The transmission of such papers by facsimile must conform with the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The CM1 facsimile center's telephone

number is (703) 308-4242, which receives papers 24 hours a day, seven days a week.

21) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (703) 308-9347. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.45 a.m to 4.15 p.m. except one day each bi-week which would be disclosed on the Examiner's voice mail system

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

SD
S. Devi
Patent Examiner
26 January 2001